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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,975	11/19/2001	Olga Bandman	PF-0227-2 CIP	9661

27904 7590 06/06/2003

INCYTE CORPORATION (formerly known as Incyte  
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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/988,975

Applicant(s)

BANDMAN ET AL.

Examiner

Richard G Hutson

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Claims 1-20 are at issue and present for examination.

***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1, drawn to human prostate-associated protease, classified in class 435, subclass 219.
- II. Claims 2-7 and 12-14 drawn to a antibody against human prostate-associated protease and methods of preparing said antibody, classified in class 530, subclass 387.1.
- III. Claim 8, drawn to a method for using an antibody to immunopurify a protein, classified in class 435, subclass 219.
- IV. Claims 9-11, drawn to a method for using an antibody to detect expression of a protein in a sample, classified in class 435, subclass 7.1.
- V. Claim 15, drawn to a method for using an antibody to treat a prostatic disorder, classified in class 424, subclass 139.1.
- VI. Claim 16, drawn to a method for using an antibody to treat a gastrointestinal disorder, classified in class 424, subclass 139.1
- VII. Claim 17, drawn to a method for testing a molecule or compound for effectiveness as an agonist for the human prostate-associated protease, classified in class 435, subclass 23.

Art Unit: 1652

- VIII. Claim 18, drawn to an agonist for the human prostate-associated protease, Possible classifications could be class 260 (organic compounds), Class 530 (proteins), Class 536 (carbohydrates), Class 423 (inorganic compounds) etc..
- IX. Claim 19, drawn to a method for testing a molecule or compound for effectiveness as an antagonist for the human prostate-associated protease, classified in class 435, subclass 23.
- X. Claim 20, drawn to an antagonist for the human prostate-associated protease, Possible classifications could be class 260 (organic compounds), Class 530 (proteins), Class 536 (carbohydrates), Class 423 (inorganic compounds) etc.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, VIII and X are structurally unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the human prostate-associated protease of Group I, the antibody of Group II, the agonist of Group VII and the antagonist of Group IX each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The polypeptides of Groups I and II are each comprised of different amino acid sequences and the agonist and antagonist comprise completely undefined chemical

Art Unit: 1652

structures. Additionally, the protein can be used to perform specific biological function(s) which are independent of the function(s) of the antibody molecule.

The invention of Group II and the Inventions of Groups III, IV, V, and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used isolate or characterize the protein of Group I.

The protein of Group I, the agonist of Group VIII and the antagonist of Group X are distinct from the methods of the Inventions of Groups III, IV, V, and VI, as these products are neither made nor used by the methods of Groups III, IV, V, and VI.

The invention of Group I and the Inventions of Groups VII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protease can be used to generate antibodies or to degrade proteins.

The antibody of Group II, the agonist of Group VIII and the antagonist of Group X are distinct from the methods of the Inventions of Groups VII and IX, as these products are neither made nor used by the methods of Groups VII and IX.

The methods of Groups III, IV, V, VII, IX and VI are independent as they comprise different steps, utilize different products and produce different results.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned

Art Unit: 1652

are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a long horizontal flourish extending to the right.

Richard G Hutson, Ph.D.  
Primary Examiner  
Art Unit 1652

rg  
June 5, 2003